

REMARKS

Claims 25, 27-29, 47, 49-51, 60, 62-64, 72 and 74-76 were previously pending. Claims 25, 47, 60 and 72 have been amended. Claims 27-29, 49-51, 62-64 and 74-76 remain unchanged. Claims 83-86 have been added. Accordingly, Claims 25, 27-29, 47, 49-51, 60, 62-64, 72, 74-76 and 83-86 are presented for further consideration.

A. Response to Rejections of Claims 25, 27-29, 47, 49-51, 60, 62-64, 72 and 74-76 under 35 U.S.C. § 103(a) as Unpatentable over Eversull in view of Gill and Nishtala.

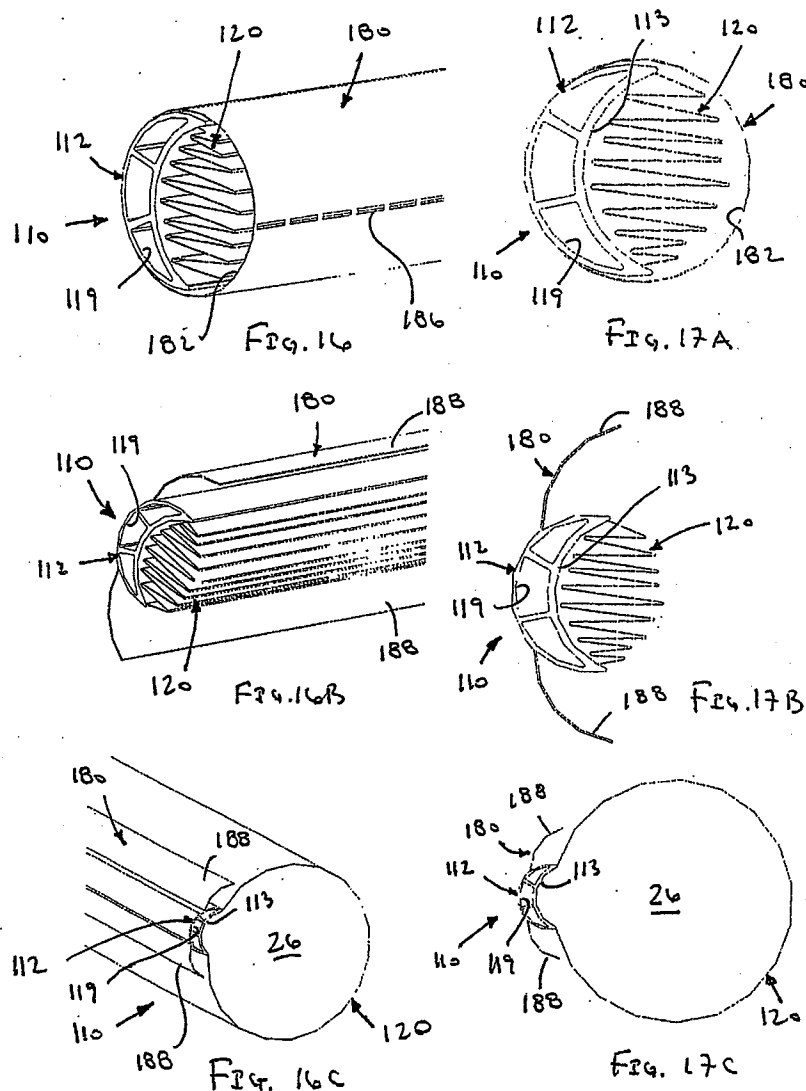
The Office Action rejected Claims 25, 27-29, 47, 49-51, 60, 62-64, 72 and 74-76 under 35 U.S.C. § 103(a) as being obvious over International Pub. No. WO/2003/090834 by Eversull et al. ("Eversull") in view of European Pub. No. 0206553 by Gill et al. ("Gill") and U.S. Pub. No. 2001/0012950 A1 by Nishtala et al. ("Nishtala"). Applicants respectfully disagree and traverse these rejections because Eversull, alone or in combination with Gill and Nishtala, fails to identically teach each and every element of Claims 25, 27-29, 47, 49-51, 60, 62-64, 72 and 74-76 both as previously and currently presented.

1. Independent Claims 25, 47, 60 and 72

The Office Action stated that Eversull, in combination with Gill and Nishtala, teaches each and every element of Claims 25, 47, 60 and 72. While Applicants traverse these characterizations, Applicants have amended Claims 25, 47, 60 and 72 to advance prosecution. Claims 25, 47, 60 and 72, as amended, recite a method of providing percutaneous access comprising, among other things, "expanding said elongate tubular structure radially around its longitudinal axis" and "releasing the elongate tubular structure from" either "a constraining tubular jacket" (with respect to Claims 25 and 60) or "a constraint" (with respect to Claims 47 and 72) and either "along a perforation" (with respect to Claims 25 and 47) or "along a score line" (with respect to Claims 60 and 72). Furthermore, Claims 25, 47, 60 and 72 recite that the jacket or constraint shares "the same longitudinal axis as the elongate tubular structure."

Eversull does not teach expansion of the elongate tubular structure radially around its longitudinal axis in conjunction with a perforated constraint, having the same longitudinal axis as the tubular structure. With reference to Figs. 16c and 17c, reproduced below, the sheath 120 cannot be expanded radially around its longitudinal axis, because its longitudinal axis is not

defined until it is fully expanded. Additionally, the alleged constraint 180 does not share the same longitudinal axis as the sheath 120, as is clearly demonstrated by Figs. 16c and 17c.



The Office Action stated that Eversull disclosed expansion of a tubular structure, a constraint and perforations. Specifically, the Office Action relied on Eversull Figs. 16-17c, reproduced above, to teach the constraining jacket or constraint and the perforations or score lines. However, the Office Action admitted that Eversull does not disclose the inflation of a balloon to expand the tubular structure. Thus, the Office Action combined Eversull with Nishtala to teach the use of a balloon catheter. However, Applicants respectfully submit that the Eversull invention, as disclosed, comprising the alleged perforated constraint, could not function in combination with a balloon catheter. In particular, because of the manner in which the

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expandable sheath 120 is folded, there is no opening within the expandable sheath 120 in which a balloon catheter could be placed. Therefore, a person having ordinary skill in the art would not have been motivated or able to combine the perforated constraint of Eversull and the balloon catheter of Nishtala with a reasonable expectation of success. *See* M.P.E.P. § 2143.02 (stating that “at least some degree of predictability is required” to establish obviousness).

For the above reasons, Eversull, alone or in combination with Gill and Nishtala, fails to teach each and every element of Claim 25, 47, 60 or 72. Accordingly, Applicants respectfully request that the rejections of Claims 25, 47, 60 and 72 under 35 U.S.C. § 103(a) be withdrawn that Claims 25, 47, 60 and 72 are passed to allowance.

2. Dependent Claims 27-29, 49-51, 62-64 and 74-76

Claims 27-29, 49-51, 62-64 and 74-76 depend from Claims 25, 47, 60 and 72, respectively, and are believed to be patentably distinguished over Eversull, alone or in combination with Gill and Nishtala, for the reasons set forth above and for the additional features recited therein. Accordingly, Applicants respectfully request that the rejection of Claims 27-29, 49-51, 62-64 and 74-76 under 35 U.S.C. § 103(a) be withdrawn that Claims 27-29, 49-51, 62-64 and 74-76 are passed to allowance.

B. Response to Rejections of Claims 25, 27-29, 47, 49-51, 60, 62-64, 72 and 74-76 under 35 U.S.C. § 103(a) as Unpatentable over Gill in view of Eversull and Nishtala.

Alternatively, the Office Action rejected Claims 25, 27-29, 47, 49-51, 60, 62-64, 72 and 74-76 under 35 U.S.C. § 103(a) as being obvious over Gill in view of Eversull and Nishtala. Applicants respectfully disagree and traverse these rejections because Gill, alone or in combination with Eversull and Nishtala, fails to identically teach each and every element of Claims 25, 27-29, 47, 49-51, 60, 62-64, 72 and 74-76 both as previously and currently presented.

1. Independent Claims 25, 47, 60 and 72

The Office Action stated that Gill, in combination with Eversull and Nishtala, teaches each and every element of Claims 25, 47, 60 and 72. While Applicants traverse these characterizations, Applicants have amended Claims 25, 47, 60 and 72 to advance prosecution. Claims 25, 47, 60 and 72, as amended, recite a method of providing percutaneous access comprising, among other things, “expanding said elongate tubular structure radially around its longitudinal axis” and “releasing the elongate tubular structure from” either “a constraining

tubular jacket” (with respect to Claims 25 and 60) or “a constraint” (with respect to Claims 47 and 72) and either “along a perforation” (with respect to Claims 25 and 47) or “along a score line” (with respect to Claims 60 and 72). Furthermore, Claims 25, 47, 60 and 72 recite that the jacket or constraint must share “the same longitudinal axis as the elongate tubular structure.”

The Office Action admitted that Gill does not disclose releasing the expanded tubular structure from a constraining tubular jacket by tearing the jacket along perforations. Because Gill fails to teach the use of a constraining tubular jacket, it also fails to teach the use of a constraining tubular jacket sharing the same longitudinal axis as the tubular structure. For the reasons expressed above in section A.1., Applicants respectfully submit that Eversull does not disclose a perforated or scored jacket or constraint “sharing the same longitudinal axis as the elongate tubular structure,” and that the perforated constraint disclosed in Eversull could not be combined with the balloon catheter disclosed in Nishtala. For these reasons, Gill, alone or in combination with Eversull and Nishtala, fails to teach each and every element of Claims 25, 47, 60 and 72.

Furthermore, the invention disclosed in Gill could not be used with a constraint. The Gill invention comprises a stem which is initially conical. An instrument or nut is then passed through the stem, uncoiling the stem, and causing it to expand to a fully open cylindrical condition. Gill, Spec. pg. 15, lines 20-24; pg. 23, lines 20-28; Figs. 4, 6, 11 and 12. As the instrument is passed through the conical stem it places longitudinal pressure on the unopened coils, causing them to uncoil in a circumferential direction. Gill, Spec. pg. 18, lines 13-15. If the coils were to be constrained around their circumference, the friction between the coils and the constraint would prevent the coils from uncoiling along their circumference in the manner required by the invention. Such longitudinal pressure on the internal surface of the conical stem would also tend to push the constraint on the external surface of the conical stem in a longitudinal direction, and therefore, into the body cavity. This would be to the possible detriment of a patient. Therefore, a person having ordinary skill in the art would not have been motivated to combine the conical stem of Gill with a constraint.

Additionally, the particular constraint of Eversull would not work in combination with a conical stem, since the constraint of Eversull requires that the diameter of the fully expanded sheath be *greater* than the diameter of the unexpanded sheath (in order to tear the perforations).

The diameter of the base of the unexpanded conical stem in Gill is *equal* to the diameter of the fully expanded cylindrical stem. Gill, Fig. 12 (chain-dotted lines representing the fully expanded stem). Therefore, a person having ordinary skill in the art would not have been able to combine the conical stem of Gill and the perforated constraint of Eversull with a reasonable expectation of success.

Moreover, the conical stem of Gill could not be combined with the balloon catheter of Nishtala. As described above, the conical stem in Gill is expanded by longitudinal movement. Gill, Spec. pg. 18, lines 13-15. The Nishtala invention, however, is directed to dilation systems which expand radially in a uniform manner. Nishtala, Spec. par. 0010 (“the dilation systems of the present invention provides [sic] for the homogeneous application of radial forces along the length of the dilating element”). Therefore, a person having ordinary skill in the art would not have been motivated to combine the conical stem of Gill with the balloon catheter of Nishtala.

For the above reasons, Gill, alone or in combination with Eversull and Nishtala, fails to teach each and every element of Claim 25, 47, 60 or 72. Accordingly, Applicants respectfully request that the rejections of Claims 25, 47, 60 and 72 under 35 U.S.C. § 103(a) be withdrawn that Claims 25, 47, 60 and 72 are passed to allowance.

2. Dependent Claims 27-29, 49-51, 62-64 and 74-76

Claims 27-29, 49-51, 62-64 and 74-76 depend from Claims 25, 47, 60 and 72, respectively, and are believed to be patentably distinguished over Gill, alone or in combination with Eversull and Nishtala, for the reasons set forth above and for the additional features recited therein. Accordingly, Applicants respectfully request that the rejection of Claims 27-29, 49-51, 62-64 and 74-76 under 35 U.S.C. § 103(a) be withdrawn that Claims 27-29, 49-51, 62-64 and 74-76 are passed to allowance.

New Claims

Applicant has added new claims 83-90. Claims 83-86 depend upon independent claims discussed above and for at least this reason is also in condition for allowance. Claim 87 is a new independent claim that recites, in part, “percutaneously inserting an elongate tubular structure having a first, folded, substantially continuous, smaller cross-sectional profile over the guidewire and into the renal collection system, wherein in the first, folded, substantially continuous, smaller cross-sectional profile the elongate tubular body forms two longitudinally extending creased

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outer sections that lie on a perimeter of the folded tubular body and facing each other and two longitudinally extending creased inner sections that lie within the folded tubular body and face away from each other.” Applicant submits that the cited art does not disclose a method with the above noted limitation and for, at least this reason, Claims 87 and dependent Claims 87-90 are in condition for allowance.

C. No Disclaimers or Disavowals

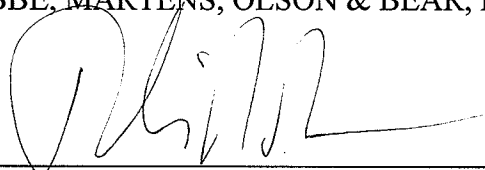
Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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